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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 01/15/2002

1)

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/786,024

Applicant(s)

Yu et al.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) 4 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicants' election with traverse of Group I, claims 1-3 and 6-11, in Paper No. 10 is acknowledged. The traversal is on the grounds that the existence of a prior art reference bears only on the novelty or non-obviousness of Group II and not on the unity between Groups I and II. This is not found persuasive because the inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. The special technical feature of the inventions listed as Groups I-VIII is a human lysozyme comprising a fragment of SEQ ID NO: 4. However, de Baetselier et al. (Accession AAR05721) teach a human lysozyme comprising a fragment of SEQ ID NO: 4 (See Alignment No. 1). Since Applicants have not contributed a special technical feature over the prior art, Groups I-V do not have a single general inventive concept and therefore lack unity of invention. The requirement is still deemed proper and is therefore made FINAL.

The de Baetselier et al. reference cited in the previous Office Action is attached to the instant Office Action.

Claim Rejections - 35 U.S.C. § 101

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-3 and 6-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants disclose the nucleotide sequences of SEQ ID NO: 3 and the deduced amino acid sequence of the protein encoded by the nucleotide sequence of SEQ ID NO: 3 as the amino acid sequence of SEQ ID NO: 4. Applicants disclose that based on homology searches that the protein of SEQ ID NO: 4 is a lysozyme which is a generic asserted utility. The specification does not specifically disclose the specific function of the protein of SEQ ID NO: 4 or its relationship to any disease. It appears that the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not

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substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

Applicant is referred to the revised interim guidelines concerning compliance with 35 U.S.C. 101, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-3 and 6-11 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 1-12 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, the claims encompass any polynucleotide having at least 70% homology to nucleotides 81-521 of SEQ ID NO: 3, encode any protein comprising the amino acid sequence of SEQ ID NO: 4, or hybridizes under moderate stringency conditions to nucleotides 81-521 of SEQ ID NO: 3. Factors to be considered in determining whether undue experimentation is required, are summarized in *re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The *Wands* factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

While molecular biological techniques and genetic manipulation techniques are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological function, biological activity, or utility of any polynucleotide having at least 70% homology to nucleotides 81-521 of SEQ ID NO: 3, encode any protein comprising the amino acid sequence of SEQ ID NO: 4, or hybridizes under moderate stringency conditions to nucleotides 81-521 of SEQ ID NO: 3 is lacking. Thus, searching for the biological function, biological activity, or utility of said polynucleotides is well outside the realm of routine experimentation and predictability in the art of success in determining the biological function, biological activity, or utility of said polynucleotides is extremely low.

The amount of experimentation to determine the biological function, biological activity,

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or utility of said polynucleotides is enormous. Such experimentation entails selecting specific nucleotides in SEQ ID NO: 3 or a polynucleotide encoding a protein comprising SEQ ID NO: 4 to change by nucleotide deletion, insertion, substitution, or combinations thereof and determining the biological function, biological activity, or utility of the polynucleotide. Alternatively, experimentation entails screening a vast number of organisms for an organism containing a polynucleotide having at least 70% homology to nucleotides 81-521 of SEQ ID NO: 3 and determining the biological function, biological activity, or utility of the polynucleotide. Since routine experimentation in the art does not include screening vast numbers of polynucleotides having at least 70% homology to nucleotides 81-521 of SEQ ID NO: 3 and determining the biological function, biological activity, or utility of the polynucleotides, where the expectation of obtaining a desired biological function, biological activity, or utility is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding the structure and function relationship of the claimed polynucleotides. Without such a guidance, the experimentation left to those skilled in the art is undue.

6. Claims 1-3 and 6-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to all possible polynucleotides which encode any protein comprising the amino acid sequence of SEQ ID NO: 4, all possible polynucleotides which have at least 70% homology to the nucleotide sequence of nucleotides 81-521 of SEQ ID NO: 3, or all possible polynucleotides which hybridize to nucleotides 81-521 of SEQ ID NO: 3. The specification, however, only provides a single representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 3. There is no disclosure of any particular structure to function/activity relationship in the single disclosed species. The specification also fails to describe additional representative species of these polynucleotides by any identifying structural characteristics for which predictability of structure is apparent. Furthermore, the specification does not disclose the nucleotide sequence that is 5' and 3' of SEQ ID NO: 3 or the amino acid sequence that is N-terminal or C-terminal of SEQ ID NO: 4. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

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Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
8. Claims 1-3 and 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
In claim 1, the phrase "having human LYC3 protein activity" renders the claims vague and indefinite because the specific activity is not known and not recited in the claims. Furthermore, in claim 1 the phrase "under moderate stringency" renders the claim indefinite because the specific conditions are not known and not recited in the claim. Claims 2, 3, and 6-11 are also rejected because the claims do not correct the defect of claim 1.

Claim Rejections - 35 U.S.C. § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:
A person shall be entitled to a patent unless --
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
10. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Jung et al.
Claim 2 is anticipated by Jung et al. (Accession V00428) since Jung et al. teach an isolated polynucleotide encoding a lysozyme wherein said polynucleotide hybridizes to nucleotides 81-521 of SEQ ID NO: 3 under moderate stringency conditions (see Alignment No. 2). Thus, the reference teaching anticipates the claimed invention.


Conclusion

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura

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Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF



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